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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/644,668	08/24/2000	Alan J. Korman	014643-010510US	5400

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EXAMINER
ROARK, JESSICA H

ART UNIT	PAPER NUMBER
1644	16

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

SDM

Office Action Summary	Application No.	Applicant(s)	
	09/644,668	KORMAN ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002 and 07 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-68* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 August 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Art Unit location and the examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Jessica Roark, Art Unit 1644, Technology 1600.

2. Applicant's amendment, filed 1/7/02, is acknowledged.
However, the amendment filed 1/7/02 is incomplete. Pages 3, 5, 8, 15 and possibly additional pages are missing. Applicant is requested to re-file the amendment IN FULL in response to this Office Action.

Claims 1-68 appear to be currently pending, and claims 1-68 are under consideration.

Sequence Compliance

3. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Drawing Requirement

4. The formal drawings filed 8/24/00 fail to comply with 37 CFR 1.84.
Please see the enclosed form PTO-948.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin.

The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

*Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.*

5. Applicant's election without traverse of Group I in Paper No. 15 is acknowledged.

However, after further consideration and review, the previous Restriction Requirement is VACATED. A new Restriction Requirement and Species Election follows.

Restriction Requirement

6. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-38, 44-50 drawn to antibodies that specifically bind human CTLA-4, compositions thereof and cells producing said antibodies; classified in Class 530, subclass 387.1; Class 424, subclass 143.1 and Class 435, subclass 334.

II. Claims 39-40, drawn to nucleic acids encoding antibodies that specifically bind human CTLA-4, classified in Class 536, subclass 23.53.

III. Claims 41-43, drawn to a transgenic non-human animal, classified in Class 800, subclass 13.

IV. Claims 51-61 and 65-68, drawn to method of inducing, augmenting or prolonging and immune response to an antigen by administering an antibody to human CTLA-4, classified in Class 424, subclass 143.1.

V. Claims 62-64, drawn to a method of suppressing an immune response in a patient, including treating an autoimmune disease caused by exacerbated activity of T cells, classified in Class 424, subclass 143.1.

The Inventions are distinct, each from the other because:
7. Groups I, II and III are different products. Antibodies, nucleic acids and transgenic non-human animals differ with respect to their structures, physicochemical properties and functions; therefore each product is patentably distinct.

8. Groups II/III and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case, the antibody product can be made using an amino acid synthesizer.
In the instant case, the cell product can be produced by fusing non-transgenic cells.

9. Groups I and IV/V are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the antibody of Group I can be used for affinity purification, in addition to the methods recited.

10. Groups IV and V are different methods. Each method differs with respect to patient populations and method steps (i.e., inducing vs. suppressing); therefore, each method is patentably distinct.

11. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search, which would not be completely co-extensive. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

12. This application contains claims directed to the following patentably distinct species of the claimed inventions:

A) If Group I is elected, Applicant is required to elect a particular anti-CTLA-4 antibody (identified by a heavy and light chain pair) and to provide the following information with respect to the elected species of anti-CTLA-4 antibody:

i) the amino acid (and encoding nucleic acid) SEQ ID NO: for the heavy chain,
ii) the amino acid (and encoding nucleic acid) SEQ ID NO: for the light chain,
iii) the applicable CDR SEQ ID NOS: of the *elected* heavy and light chains, and
iv) whether the antibody does or does not block binding of CTLA-4 and a B7 ligand.

These species of anti-CTLA-4 antibodies are distinct because each antibody possess a unique structure as determined both by its heavy and light chain sequences, and by the pairing of those sequences to produce the antigen binding site. Currently, claim 1 is generic.

B) If Group I is elected, Applicant is required to elect a particular pharmaceutical composition comprising the anti-CTLA-4 antibody elected supra by identifying whether the pharmaceutical composition further comprises one of the agents recited in claims 48-50.

These species of pharmaceutical compositions are distinct because each includes distinct ingredients. Currently, no claim is generic.

C) If either Group IV or Group V is elected, Applicant is required to elect a method of treating a specific patient population with a specific pharmaceutical composition (e.g. an election of a prostate cancer patient population and a pharmaceutical composition comprising an antibody that blocks binding of CTLA-4 to a B7 ligand, a bispecific antibody, a tumor antigen and an antigen-loaded dendritic cell vaccine would correspond to an election of instant claims 51-54, 56-57 and 65-68).

These species are distinct because each method differs from the others with respect to etiologies of the disease, the patient populations involved, their therapeutic endpoints and the ultimate composition administered; thus each specific method o represents patentably distinct subject matter. Currently, claim 51 is generic.

Applicant is required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

13. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
Technology Center 1600
January 16, 2003

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
1/16/03